

SPL ER/DL Team

May 11, 2011

Minutes –Pat's notes

Date: May 11, 2011, 1 pm

Teleconference information:

USA Toll-Free 866-213-2145

Access code: 273 8216

Chair for this meeting: Michelle Halliez

Presenter: Tom Bizarro, First Data Bank

Topic: Downstream uses of SPL and drug data

1. Overview of FDB

- a. Drug knowledge base company – made available to anyone in the industry with a need for drug data
- b. Traditional customer was the pharmacist-
- c. Now: Customers: used by MD, nurses, home health care, quality development, electronic medical records, e prescribing, pharmacy dispensing, privacy claim adjudication, consulting pharmacists, wholesalers,
- d. Knowledge base: drug data and 30 critical modules provided to systems developers to use in their applications (drug allergy checking, IV compatibility, drug drug compatibility)
- e. FDB business focuses on the data, not a software development
- f. Has a couple of applications, but not focus
- g. FDB has 35 clinical pharmacists.
- h. Other staff (ie customer service reps) are pharmacy reps.
- i. Understand need for quality/accuracy of data.

2. How does FDB get all its data in its databases

- a. Sources:
 - FDA approved labeling
 - Contacts with pharma companies
 - Data acquisition collection groups
 - In the past, used USPI
 - electronic SPL provides huge advancement in making this data correct and current.
 - OTC monographs
 - References: Am Hospital Services
 - Harriet Lane and Briggs
 - Electronic journals and in print
 - Data is then provided in a manner useable by real time applications.
- b. Want to keep data current. Look for triggers to alert them of when things should change.
 - want to keep the data current
 - often it is a push of data to FDB at first approval of product.
 - Updates to SPL
 - Medwatch
 - Treatment guidelines
 - CDER new

- Will go out and look for changes. Will review monographs on a cycle, to find changes even if trigger hasn't happened.
3. SPL: This is really valuable to FDB and to the patient
 - a. Electronic nature helps assume timely update
 - Download automatically and disperses to FDB clinicians
 - Have systematic way to review for changes.
 - Highlights
 - b. FDB is active in industry groups related to SPL, to stay in touch with current situation.
 - c. Provides ready access to less popular products.
 4. Users
 - a. customers expect timeline information
 - b. Third party payers make up 95% of all drug sales.
 5. Codification of labeling
 - a. Benefit users to have more data available quicker. Allows easy identification to change
 6. Data details:
 - a. Provide data at NDC level...but also aggregates data.
 - b. National vocabularies
 - c. RxNorm: non-proprietary way to describe a drug product. Provides a common language that is more specific than an NDC. Identifies product that is not manufacturer specific. Has a common identifier for the drug product.
 - Physicians don't know/care about NDCs
 - Care about national vocabularies.
 - They would like RxNorm become part of SPL
 - d. Really value SPL as source of data
 7. FDB's association with CMS
 - a. CMS is a large customer of FDB
 - b. Almost an advisory relationship. FDB understands need for information.
 - c. FDB does not have any influence over CMS policy, but they do provide information on how data is used by the industry.
 - d. CMS provides information about billing units for rebates. These are sometimes in conflict with billing units established within NCPDP.
 - e. CMS is not required to follow NCPDP standards. There are discrepancies between the billing amounts in CMS rebate amount and billing unit used by the dispensing pharmacy that is established by NCPDP. There could be issues around this.
 - NCPDP quantity for a refilled syringe quantity is amount in the syringe....ie 3 ml.
 - Manufacturer says billing unit is 1 syringe.
 - Change must be made by third party to make the conversion.
 - f. Unit of administration at the bed side must have a bar code or identifier. It is hard to get this information for the inner packages. FDB needs this information because the bar code needs to be in FDB database. If this doesn't exist, then it won't be available at the bedside for use in records and billing. This could limit the use of the product.
 8. Where does FDB get their photos
 - a. They have a photo/imprint option.
 - b. FDB takes the photos themselves.
 - c. Contracts are in place to get access to these products. Difficult process
 - d. Have high quality standards for the photos.

- e. Sometimes it is hard to get access to some products, and they have used photos provided by manufacturers.
 - f. Do they also take photos of the packaging? They have done a lot of research with customers to see what they would like to see. They vary by the dosage form.
 - g. Image database is most often used in the pharmacies – especially at the high volume pharmacies. Not so much in hospitals.
 - h. No access to foreign products (ie Canada). Too expensive to maintain.
9. NLM initiative = Pillbox. FDB is excited about this because it will be great to have a high quality photo of the product to be available – common standards, electronic, available.
10. How should a manufacturer go about correcting FDB data for their product? If you see issues with the data that you are seeing in FDB data, please contact FDB to discuss the data issue. They welcome questions/discussions.
- a. Strive to have a single point of contact with a manufacturer.
 - b. Go through the company's point of contact.
 - c. Which division do they typically work with. It varies. Sometimes regulatory, sometimes marketing. Hard when there are mergers/acquisition.
 - d. Try to keep track of changes with turnover, but it is hard. It is really critical to make sure that information gets updated in a timely manner.
 - e. What kinds of information do they need to get from the manufacturer?
 - That there is a labeling changes, in general. FDB will then look up the changes
 - Would like to have advance notice of changes, so that information is made available asap.
 - Some data is updated daily.
 - Clinical data is updated weekly or monthly.
 - How to find out who is the point of contact within your company. Contact FDB at 800-633-3453. Identify yourself as a manufacturer and ask the for the FDB data acquisition coordinator...you can then ask them who your rep is.
11. SPL. Do you do any transformation of the SPL data?
- a. They do link the data to transformational system
 - b. Clinical pharmacists will review and input data from the text, for example the interaction data. They use many sources of information about the severity of the interaction.
 - c. They will potentially change/generalize DLDE data – robins egg blue....to blue.
 - d. They have found discrepancies within the SPL data itself.
 - e. FDA has been willing to speak with FDB to determine how they use the data...to make sure that they drive changes in directions that best meet customer needs.
12. Takeaway message: SPL has a huge impact on making drug information available to patients. This is a huge step forward. Having this information available is so valuable and please work within your companies to make this information available and correct.